TAB 8

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UNPUBLISHED OPINION. CHECK COURT RULES BEFORE CITING.

Court of Chancery of Delaware.

MERCK & CO., INC., Plaintiff,
v.
SMITHKLINE BEECHAM PHARMACEUTICALS CO., Smithkline Beecham Holdings Corporation, Smithkline Beecham Corporation, and Smithkline Beecham Biologicals S.A., Defendants.

No. C.A. 15443-NC.

Aug. 5, 1999.

Richard D. Allen, Mary B. Graham, Julia Heaney and Bradley J. Enna, of Morris Nichols Arsht & Tunnell, Wilmington, Delaware; of Counsel: Paul D. Matukaitis and Kevin J. McGough, of Merck & Co., Inc., Rahway, NJ; Attorneys for Plaintiff.

Richard K. Herrmann and Mary B. Matterer of Blank Rome Comisky & McCauley LLP, Wilmington, Delaware; Donald R. Dunner, Susan H. Griffen, Howard W. Levine, John R. Alison and York M. Faulkner of Finnegan Henderson Farabow Garrett & Dunner LLP, Washington, D.C.; of Counsel: James K. Grasty, Yuriy P. Stercho, of Smithkline Beecham, Philadelphia, PA; Attorneys for Defendants.

OPINION

CHANDLER, Chancellor.

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FN* The following table of contents is included solely for the purpose of aiding the reader and is not part of the Court's official opinion. Therefore, all publishers should feel comfortable repaginating this table for any subsequent publication.

*1 This lawsuit involves claims of misappropriation of a trade secret--the process for producing a vaccine to prevent varicella (commonly known as chicken pox). After a two week trial and post-trial submissions by the parties, this is the Court's findings of fact and conclusions of law. In short, I find in favor of plaintiff Merck on its claim of misappropriation of a trade secret and I dismiss defendant SmithKline's affirmative defenses and counterclaims for various reasons, including laches and the statute of limitations.

The Court's decision is organized as follows. Part I describes the parties, the nature of Merck's claims, and the background facts, including my findings of fact where the parties disagree. Part II represents my analysis of these claims and my conclusions of law. Part III describes the facts relating to SmithKline's affirmative defenses and counterclaims, including my findings of fact, where necessary. Part IV sets forth my analysis of these defenses and counterclaims and my conclusions of law. Finally, Part V summarizes all of these conclusions.

I. FACTS

A. The Parties and The Nature of the Action

The varicella vaccine which is the subject of this lawsuit was developed by the Research Foundation for Microbial Diseases of Osaka University ("Biken" or the "Foundation") using a strain of virus known as the Oka strain. Plaintiff Merck & Co., Inc. ("Merck") seeks to enjoin Defendants SmithKline Beecham Corporation ("SB Corp ."), SmithKline Beecham Biologicals S.A. ("SB Biologicals"), formerly called "RIT," SB Pharmaceuticals Company ("SB Pharmaceuticals"), and SmithKline Beecham Holding Corporation ("SB Holding"), from marketing varicella vaccine in the United States and Canada. [FN1]

FN1. SmithKline & French ("SK & F") was the actual party to the Option Agreement. RIT was the entity within SK & F responsible for developing vaccines for the company. SK & F, RIT and the defendants are collectively referred to herein as "SB".

Biken is the Japanese entity that entered into license agreements with both SB and Merck regarding the Oka strain. The Research Institute for Microbial Diseases of Osaka University (the "Research Institute" or "Institute") performs basic scientific research in vaccines and preventive medicines, while Biken commercially develops products resulting from that research (Tr. 772-74). [FN2]

FN2. Definitions. For the sake of clarity, what follows is a glossary of terms that I employ freely in the course of this Opinion. Antigen: both dead and live virus--measured in Elisa units. BSA (bovine serum albumin): albumin is the major protein in serum and serves as a carrier to the cells of the other serum nutrients; component of FBS that can be measured (see definition of "Serum or FBS" below). Cell culture: growing cells as "host" cells for virus in an artificial environment (e.g. laboratory or production). CPE (cytopathic effect): visible consequence of cells being infected (term is used in a culture system). Culture vessels: the vessels in which cells are being grown. Growth or cell culture medium: mixture of sugars, salts, amino acids, vitamins and other nutrients for the host cells. Kinetics: refers generically to the split ratios (or MOI's) and harvest times of the viral passages. Maintenance medium: separate culture medium tailored more for cells no longer growing but which have been infected with virus. MOI (multiplicity of infection): ratio of infectious units to uninfected cells at the initiation of a viral passage (measured by PFU's and counting cells). The terms MOI and split ratio are close in meaning (see "Split ratio" below) and relate to the ratio of infected cells that are used to infect uninfected cells. SB speaks of split ratio as a ratio of the surface area of infected cell sheet to the cell sheet being infected. MOI looks at that ratio in terms of the number of infected cells rather than surface area. When the cell sheet is 100% infected, split ratio and MOI are the same. When the cell sheet is less than 100% infected, the split ratio is higher than the MOI--e.g. Biken's REDACTED split ratio resulted in an MOI of REDACTED because Biken's cell sheet was about REDACTED infected (Tr. 954-55). PDL (passage doubling level): number of population doublings that the cells have undergone since the cell culture was started. Potency: strength of vaccine or amount of live virus--measured in titer or plaque forming units (PFU's). Serum or FBS (fetal bovine serum): collection of proteins that are added to the growth or maintenance medium to enhance cell growth and maintenance. As noted above, BSA is

the major protein. Split ratio: in the context of viral passaging, ratio of surface area of the infected cell culture to the surface area of the target cell culture to be infected; in the context of cell culturing, ratio of surface area of the fully grown cell culture to the surface area of the fresh, unoccupied vessels into which these cells are being placed. Titration: method for measuring the amount of live virus. Viral passage: cycle of virus growth in cell culture, which involves incubation at a set temperature and time period in culture vessels.

B. Vaccine Production Processes

Viruses are microorganisms consisting of genes wrapped in layers of proteins (Tr. 11). [FN3] Viruses reproduce by infecting a host cell and pirating the genetic "machinery" (DNA and RNA) of the cell to make more viruses (Tr. 12-13). When viral infection occurs in humans (or animals), the infected host cells are destroyed, resulting in disease or death (Tr. 13-14). The human immune system, however, may respond and cure the infection before disease spreads. A viral vaccine uses a form of virus to trigger an immune response without causing disease (Tr. 15). There are three general types of viral vaccines: recombinant DNA (e.g., hepatitis B vaccine); inactivated or killed (e.g., hepatitis A vaccine); and live attenuated (e.g., measles, mumps, rubella, and varicella) (Tr. 16-19). A live viral vaccine uses a virus that has been weakened through attenuation. Attenuation consists of passaging (i.e., reproducing) the virus numerous times by growing it in atypical cells, such as guinea pig cells, and finding a passage level, if possible, at which the virus is strong enough to generate an immune response but too weak to cause disease. The viruses used for live attenuated vaccines are generally both fragile and complex in structure (Tr. 20-21). Varicella, the virus that causes chicken pox, is among the largest and most structurally complex of viruses (Tr. 12, 1942-43).

FN3. Citations in the form "Tr.___" refer to the trial transcript and "dep. ___" to deposition pages of the identified witness. Other citations are self-explanatory.

***2** The American Academy of Pediatrics and other authorities have long expressed a need for a vaccine to prevent chicken pox, because it can be life-threatening and accounts annually for many illnesses. While vaccines were developed for other common childhood viral illnesses in the 1960's (measles, mumps, rubella), attempts to develop a chicken pox vaccine were not successful.

A live viral vaccine is made from a stock of attenuated virus and host cells from a bank (Tr. 70). The basic steps are: (1) preparing additional quantities of the attenuated virus by further passaging; (2) growing host cells in culture vessels (such as Roux bottles, T-flasks, cell factories, or cell cubes); (3) infecting the host cell culture with virus under conditions causing the virus to multiply; (4) harvesting the virus from the infected cell culture; and (5) clarifying the harvested material to make bulk vaccine (Tr. 64-66). The bulk vaccine is generally frozen and at a later time processed into vials of final vaccine and is then lyophilized, i.e ., freeze dried, to remove moisture, stabilize the vaccine, and facilitate handling until the vaccine is reconstituted for administration to humans (Tr. 1429-30).

A commercial production process for making a vaccine must be able to produce large quantities of potent, safe vaccine from limited supplies of materials. The vaccine must be of consistent quality and characteristics and satisfy regulatory requirements. A commercial production process must also meet practical, cost, and safety concerns. It also must be robust enough that the quality of the vaccine is maintained even when the process is run on a frequent basis in a manufacturing environment where relatively unskilled labor may perform the process, and where equipment and materials may cause variations in the product (Tr. 52-64; PTX 700-748).

Development of a commercial vaccine production process is difficult and lengthy. Typically, basic scientific principles are first explored and established in a research laboratory and then passed on to scientists or engineers working in a production development area (Tr. 920-21). These developers conduct further experiments in an environment that takes into account the requirements of a commercial production process, although initially at smaller scale (Tr. 922-23). If the developers achieve some success, experiments will normally be conducted at production scale in order to test the parameters before making the expensive commitment to begin consistency lots (Tr. 923-27). Consistency lots are

consecutive lots (generally five) produced by the same process in all five lots. Consistency lots are required for FDA approval in order to show that both the process and the vaccine produced (which then undergoes clinical trials) are consistent.

In both the research laboratory and subsequent development, the possible steps of the vaccine process are explored, and the parameters and conditions, including materials and equipment, determined by rigorous experimentation. The possibilities are numerous and all of the process steps are interconnected and not easily studied independently. This non-linear characteristic means that changes made to the parameters of one step may require changes to other steps, thus complicating and lengthening the development effort (Tr. 127-28).

*3 In any scientific experimentation to establish a production process, the experiments to establish the parameters and conditions must be repeated in order to verify results (Tr. 924-25). This is particularly true for biological processes, which include vaccines, because they experience significant variability, so that repetition and statistical analysis of results is essential (Tr. 924-25). If more than one parameter is varied in an experiment, interpretation of the results is even more difficult.

Titration, the method for measuring the amount of live virus (i .e., potency or titer) present in a sample, further complicates the development process for two reasons. It is very time-consuming, requiring six or seven days just to perform the part of the titration involving the viral infection and almost as much time beforehand to prepare the cell culture for infection. It is also imprecise, such that even a well-developed titration method experiences variability on the order of about 20% (Tr. 115-16). Where a developer cannot rely on the titration results, such blindness in comparing experiments, in addition to the need for numerous repetitions, will seriously impede development (Thysman dep. 596; Duchene dep. 206-07).

C. Complications in Making Varicella Vaccine

The varicella virus has characteristics that make production of vaccine more difficult than for other common viruses. Varicella is an intracellular virus, at least in artificial (i.e., production and laboratory) environments--meaning that when the varicella virus infects a cell culture, the virus does not leave the cell and continue with further infection, but rather remains stuck as buds on the outside surface of the cell (Tr. 41-43, 1638). This intracellular characteristic makes producing varicella vaccine more complicated. At the point of beginning a varicella virus passage, in order for the infection to be efficient, the cells must be at the point of confluency, i.e., the cells must cover the entire surface of the culture vessel and touch each other (Tr. 76, 92-93). After the passage of varicella virus is completed, unlike in production of other vaccines, the infected cells must be broken in order to release the varicella virus, such as by sonication, homogenization, or other means (Tr. 132-35).

A further complication is that in a varicella vaccine production process, after the infected cells are broken, the varicella virus remains attached to the cell debris. At the same time, it must be assumed that there could be some whole cells remaining. Any such remaining whole cells must be removed from bulk varicella vaccine by clarification for safety reasons (the safety concern is that injecting whole cells into people could potentially cause tumors (Tr. 136-37)). The difficulty for a production process is that the virus may unintentionally be removed when whole cells are removed (called "clarification") because large aggregates of cell debris (to which the virus remains attached) may also be removed (Tr. 137-40). Also, whole cells can vary in size and the clarification conditions must be sufficiently rigorous to remove even the smallest whole cells.

*4 Yet another complication is that only about one in 100,000 to one in 1,000,000 of the varicella particles grown in a cell culture are actually infectiou (as compared to measles or mumps where about one in 1,000 of the viruses leaving a cell are infectious) (Tr. 43-44). Because of this natural inefficiency of a varicella infection in cell culture, the parameters of the varicella virus growth cycle (i.e., passaging) in a commercial production process must have carefully tailored timing, temperature, composition of the medium, and multiplicity of infection ("MOI") in order to maximize efficiency of the infection and, ultimately, the quantity of vaccine that can be produced from the limited seed stock (Tr. 108-18). For varicella, viral passaging involves first creating an intermediate population of virus at a given MOI or split ratio and then using

that intermediate virus population as starting material for production of the bulk vaccine (Tr. 71-72).

Furthermore, varicella's structural complexity negatively affects its physical stability, such that outside the human body its infectivity decreases more rapidly than other viruses under comparable conditions (Tr.1943). This poor stability (i.e., loss of titer) impacts a number of process steps, including the steps of breaking open the cells, clarification, and lyophilization, because the secondary drying cycle occurs at elevated temperatures where the risk to stability is greater (Tr. 1458). The presence of greater amounts of cellular debris in varicella vaccine (due to its intracellular nature) may also impact the choice of lyophilization parameters and the vaccine's stability (Tr.1940-41).

For varicella, any fetal bovine serum ("FBS") used in the culture medium to help grow and maintain the cells creates a safety concern. FBS contains bovine serum albumin ("BSA"), generally considered to be unsafe for injection into humans (Tr. 120-21). Any washing technique must be sufficiently rigorous to get rid of the substantial amounts of FBS that are trapped within the cell sheet in order to get rid of all BSA (Tr. 122-23). At the same time, cells are fragile and washing must not be so harsh as to break them prematurely (Tr. 125). If the cells are broken during washing, the varicella virus will also be discarded with the FBS in the washing solution (Tr. 125). [FN4]

FN4. There are different washing techniques. A "spin wash" involves centrifuging infected cells in the rinsing or detachment liquid solution, which washes away the culture medium (including FBS) that may be trapped in the cell sheet and separates the cells from the liquid by centrifugal force. A "prewash" is a wash of the surface of the infected cell sheet with a washing solution (e.g., a phosphate buffered saline solution) prior to detachment and harvest of the infected cells.

D. Biken's Development and Licensing of the Oka Strain of Varicella Virus

The Oka strain varicella virus was isolated in 1970 by Dr. Michiaki Takahashi of the Research Institute (Tr. 779). Takahashi attenuated the strain and produced in his laboratory a varicella vaccine that was successfully tested in clinical trials (Tr. 779-80). In 1974, Takahashi published an article concerning his work with the Oka strain and his initial success in developing a vaccine in his laboratory (TX1393). This publication prompted interest by a number of companies, including SB and Merck, which on their own had been attempting (unsuccessfully) to develop a varicella vaccine (PTX325, PTX336).

***5** In 1975, SB obtained from Biken an option agreement giving SB the exclusive right for a two-year period to study the Oka strain (PTX306). SB received from Biken a sample of the strain as well as confidential technical information on the laboratory process developed by Takahashi (PTX1). That option agreement was subsequently extended twice (PTX324, PTX338), but ultimately lapsed. [FN5]

FN5. See pp. 68-78 infra.

In late 1980, Biken and Merck entered into a licensing agreement granting Merck nonexclusive rights in the United States and Canada to the use of the strain and the Biken know-how (PTX551). Through subsequent amendments, Merck's rights in the United States and Canada became exclusive, and Merck received nonexclusive rights elsewhere. In February 1982, Biken and SB entered into a licensing agreement granting SB nonexclusive rights in Europe in the Oka strain and Biken know-how. The agreement states that it sets forth "the terms under which [Biken] will provide to" SB the trade secrets. The agreement grants rights only in the contract territory (PTX552). Biken offered SB nonexclusive rights in the United States and several other countries, but SB chose instead to accept nonexclusive rights in Europe (PTX472; PTX 552). SB later was able to acquire additional nonexclusive rights in other countries of the world, but not the United States or Canada (PTX569). By the time SB acquired those nonexclusive rights, Biken had already granted Merck exclusive rights in the United States and Canada.

Biken intended to produce a commercial varicella vaccine and retained for itself exclusive rights in Japan and Korea and nonexclusive rights elsewhere (until it granted Merck exclusive rights in the United States and Canada). Thus, in 1979, Takahashi's laboratory process was transferred to

the production facility at Kanonji, Japan, which thereafter developed a process for producing varicella vaccine on a commercial scale (Tr. 780, 842).

In 1986, Biken received approval from the Japanese Ministry of Health to sell its varicella vaccine for healthy individuals and subsequently received similar approval in Korea (Tr. 781, 783). Biken was the first entity to be approved to sell a varicella vaccine for healthy individuals, although SB received approval to market the vaccine to immunocompromised individuals in 1984. As of 1990, the commercial process developed at Kanonji had a capacity of REDACTED doses per year and Biken was actually producing between REDACTED doses annually (Tr. 783).

E. SmithKline's 1985 Laboratory Process

Prior to obtaining the Oka strain from Takahashi in 1975, SB had worked with other strains of varicella virus (PTX632, A554-604). SB was not successful, however, and sought the Oka strain as the "strain of choice for large scale production for wider application in normal children and possibly in elderly" (TX2220; Tr. 1664). After receiving the strain, SB first attempted to make vaccine in its laboratory. The contemporaneous documents that still exist from the late 1970's show that SB in fact looked to Biken and benefited from Biken's help. When Erik D'Hondt in 1975 began his laboratory work at SB with the Oka strain, he received Takahashi's laboratory method, which included such information as Biken's use of for incubation of the varicella virus (PTXI). Although SB's experience with other varicella strains was to incubate at REDACTED SB adopted Biken's REDACTED incubation for the Oka strain (Tr. 1886-88, 1893-94; TX1396, TX2163).

***6** SB asserts that it was interested only in the Oka strain and not in Takahashi's method for producing a vaccine (SB Br. n.5) and points to a 1974 SB document stating that Biken has "very little experience in sonication" (TX 2164). Nevertheless, in 1977 and again in 1978, Dr. N. Zygraich and Dr. Stan Huygelen, D'Hondt's supervisors, wrote to Takahashi that SB was "unable to get cell-free virus using our regular sonication method" and requested information on Biken's sonication method (PTX3, PTX8). Biken provided the requested information both times, including details on the specifications of its sonication equipment (PTX4, PTX9). In addition, SB's and Biken's records reflect that Huygelen and Takahashi exchanged visits relating to varicella at least in 1979 and 1982 (PTX12, PTX13, PTX 14, PTX187, PTX188). D'Hondt later acknowledged his dependence on Biken in a memo to management that stated that the procedure used to prepare experimental batches "was a mixture of the Takahashi data and our own data and experience" (PTX21).

SB made its first batch of Oka strain varicella vaccine for use in clinical trials in D'Hondt's laboratory in 1977 (Tr. 1692-93). Several more batches were made in the laboratory in late 1979 and clinically tested (Tr. 1697-99). These were all small-scale.

SB sought registration in Europe of its varicella vaccine for immunocompromised children in 1983 and around that time decided to transfer its varicella vaccine process from R & D to production. Michel Duchene, the SB employee in charge of the transfer, testified that SB's attempt to make that transfer "faced a great deal of difficulties ... particularly linked to the great sensitivity of the virus," and that SB experienced "numerous failures" (Duchene dep. 32, 44). As a result, Duchene had to "reproduce to the letter everything that was done R & D," rather than use SB's standard manufacturing practices, in order to achieve adequate viral yield (id. at 44, 50-55).

Although SB already had extensive experience in the development of large scale manufacturing processes for producing vaccines (SB Post-tr. Br. at 5), SB was not able to use commercial production parameters for its 1985 process for varicella vaccine (Duchene dep. at 69). For example, SB was not able to adapt the varicella process to normal working hours, but rather had to make "a strict application of the approach employed by R & D" which involved production outside of normal working hours (id. at 61; PTX17) (inoculation of REDACTED viral passage on REDACTED); Biken itself had this same need, however. SB also had to adopt the same small scale of production in its production department as it had used in D'Hondt's research and development laboratory, whereas for other vaccines, SB was able to scale up REDACTED (Duchene dep. at 36). D'Hondt stated that SB's 1985 process was "more

lab-scale than industrial" (PTX632). Biken, on the other hand, was producing REDACTED doses of vaccine per year in 1990 (Tr.2010).

*7 SB's "Laboratory Method" for varicella vaccine (written in 1985 and approved by Duchene) was the standard operating procedure ("SOP") that confirmed the parameters SB had been applying for production of varicella vaccine for the immunocompromised market (PTX17). The 1985 process did not specify the BSA content of the vaccine produced, and the vaccine in fact did not meet the WHO standard later adopted by SB (based on concerns) to have less than 25 ng/dose of BSA (Tr. 534, 1929).

Because the market for immunocompromised individuals was very small, SB was able to make varicella vaccine for that market, even though its process had not been designed to produce large quantities of vaccine at reasonable cost (Tr.1915-17). SB did not expect that the vaccine would be a commercial success, and knew that its sales would be limited (Tr.1915-16). From 1985 through 1992 SB actually sold a total of only REDACTED doses to satisfy the "market need" (TX2616).

F. SB's Efforts to Redevelop the 1985 Process

I note here, by way of introduction, that SB provided at trial a list of fourteen steps in its production of the varicella vaccine. For each of the steps it claimed that either: (a) SB independently developed it; (b) SB used it in its 1985 process or disclosed it to the FDA by 1983; (c) Biken had published it; or (d) the step was either not disclosed or SB's process differs from what was disclosed by Biken. Because Merck need only prove that SB misappropriated one of the steps to obtain an injunction and because addressing all of the steps would lengthen this opinion to the over 900 pages submitted by the litigants [FN6] (almost half of which are SB's proposed findings of fact and conclusions of law), I will limit my discussion as much as possible to just two of these steps. Therefore, I need not reach an opinion as to whether SB misappropriated any of the remaining twelve steps.

FN6. Although I lament the length of the submissions, it is understandable given the complexity of the issues and the tremendous volume of documents and exhibits introduced at trial. Moreover, I thank counsel for providing the post-trial briefs on hyper-linked CD-ROM discs. It would not have been possible to review the record and the legal arguments and issue this decision as promptly without this high-tech advantage.

1. SB's Initial Work and the VA30 Series (VA30-34)

In anticipation of seeking approval of its varicella vaccine for use in healthy individuals, SB continued after 1985 to try to develop a commercial production process. The 1985 varicella process was the "starting point" for that effort, and the task facing the developers was "essentially to move from the [1985] process to a large-scale commercial production process" (Didelez dep. 18, 304).

Duchene and Luc Ostyn began the work, with Jean Didelez taking over for Duchene in 1987 or 1988 (Didelez dep. 17). In the view of Didelez, the 1985 process was "more close to a lab process than an industrial process" and "was adapted to discount production but not to large scale production" (Didelez dep. 10-11). It was "quite clear" to him that "you could not increase the size, the batch size with this type of process" and that "you had to redevelop a new process" (Didelez dep. 61-62).

In 1986, SB received an additional supply of Oka varicella seed from Biken, Oka M2001, along with documentation about Biken's process for making the seed (D'Hondt dep. 435-36; TX2312, TX2485). SB used this new seed as the starting material in its production of experimental lots beginning in 1986. During the period from 1986 through spring 1989, several experimental bulk lots were made (Ostyn dep. 30) and numerous other experiments were performed (TX2731).

*8 Instead of leading SB to its goal, the result of this work was that the production process was "once again brought into question" (Ostyn dep. 30, 223) The Product Development Committee ("PDC"), SB's top management committee responsible for "defining the strategy [and] setting the priorities" for varicella and other vaccines, reported as of the end of April 1989 that in the technical development "there is no consistency of production yields" and "[f]urther work has to be undertaken" (PTX37).

One reason the production process was again brought into question was "the size, which was not sufficiently industrial" and did not allow production of REDACTED (Ostyn dep. 31, 223-24). A separate concern was that the lots had "high BSA content" (id.). The concern over BSA stemmed from SB's decision in early 1988 to meet the draft standard promulgated by the WHO for the maximum amount of residual BSA (TX2717; Ostyn dep. 31). This decision created a further obstacle in the development--"it was not simple to produce a vaccine with a low BSA content" (Ostyn dep. 31).

2. Didelez's Fall 1989 Attempt at a "Most Plausible Scheme"

On September 21, 1989, Didelez prepared "a fast varicella position and a proposal for a program" for his superiors, Christian Vandecasserie and Jean Stephenne, Vice President of Production and R & D (PTX40; Tr. 2298). The proposal called for production of two lots of bulk vaccine "following the most plausible scheme today," and completion of development by the end of 1989. Then, in January-March 1990, Didelez expected there would be production of "3 lots following a refined method" (id. at PTX40).

Didelez's "most plausible scheme" called for: (1) new kinetics--"MOI REDACTED last passage" and "harvest towards REDACTED hours"; (2) reduction of BSA, by substituting REDACTED for REDACTED as the maintenance medium; and (3) clarification by REDACTED instead of centrifugation which SB had been using (id.). Didelez did not propose any particular culture vessel.

The points addressed by Didelez's most plausible scheme were fundamental. MOI is critical, because it directly affects the quantity of vaccine that can be produced (Tr. 117). An MOI of REDACTED uses half as much viral seed (the starting material) relative to the amount of uninfected cells and infects at a slower rate, as compared to an MOI of REDACTED (Tr. 110-14). Thus, REDACTED provides twice as many doses as REDACTED assuming the pfu titer per ml of bulk is maintained. Maintaining the pfu's was the challenge, and it could not be known without experimentation whether that was possible (Tr. 115-17). The harvest time was relevant to SB's concern to harvest during the day (Tr. 545-46). BSA had to be reduced because of the WHO standard, while clarification was critical to removal of whole cells.

SB proceeded in October 1989 to make the two planned experimental bulk lots (VA35 and VA36) with "the most plausible scheme," and two additional experimental lots (VA37 and VA38) in early 1990 with different kinetics (Ostyn dep. 294-95, 313, 318-21, 325-32, 338-40, 342-44). Three different culture supports were tested: REDACTED These experiments failed to meet expectations. In some instances, no conclusions were noted; in others, it was noted, it was "impossible to draw conclusion[s]" (PTX47) or there were "no titers" (PTX47). BSA was "still quite high" (Ostyn dep. 335).

*9 The October 1989 trial gave titer for an MOI of REDACTED of only half that using an MOI of REDACTED pfu versus REDACTED pfu prior to clarification (PTX45). This was the only trial of an MOI of REDACTED prior to the visit by Biken to SB in December 1990.

SB asserts that, because the values in that one trial "after clarification were identical, SB concluded that there was not a significant difference between the REDACTED ratios" (SB Br. 15). Because of the possibility of variability, (Tr. 2283-84), however, SB witnesses testified that it was necessary to perform multiple experiments (Thysman dep. 222-23, 431; Didelez dep. 669, 720-21). It is important to note that the comparison in that trial was with REDACTED hours, not REDACTED hours that SB had established as optimal (PTX45). So SB could not have concluded that REDACTED hours was just as good as REDACTED hours at this stage of development. SB did not make that comparison until after the Biken visit (PTX120).

3. Didelez's New "Most Plausible Scheme" and the Need for a "Fresh Start" in March 1990

After this experimentation, on March 2, 1990, Didelez wrote a memo to his superiors (PTX56), the purpose of which was to provide a "summary of the status of the development and information of the next experiments to be conducted" (Didelez dep. 703). The memo recites that he was attaching "the production scheme retained as being the most plausible."

That scheme contemplated using REDACTED and, unlike the September 1989 scheme, either REDACTED as the MOI for the last viral passage, with "[h]arvest depending on timing to be determined" (PTX56). (Didelez dep. 703-04). While SB claims REDACTED was compared to REDACTED because it had more experience working with a REDACTED MOI, I do not find that credible. If SB had determined a REDACTED MOI was optimal and preferable to REDACTED because it yielded twice as much virus, it would only be natural for SBI to use REDACTED as its new base line.

Didelez, having concluded that SB's development needed a "fresh start," in March 1990 hired Pierre Thysman, a recent graduate in chemical engineering. (Thysman dep. 10-13, 214-16). Thysman's first work was application of the "production scheme" proposed in Didelez's March 2 memo (Ostyn dep. 357-58). Had the scheme turned out well, Didelez planned that "batches will be produced in May to June [1990] adopting the optimal parameters that have been decided upon" (Ostyn dep. 348; A265). However, the scheme did not work at all. In Ostyn's words--"[a]ll the results were bad," "catastrophic, < <currency> >7D "very weak," or "all weak" (Ostyn dep. 359-60, 381, 388).

SB asserts, based on trial testimony of Didelez, that from these trials it knew all along the kinetics that it would use (SB Br. 16-17). According to SB, it had decided from the single trial in October 1989 to use kinetics of REDACTED MOI and harvest at REDACTED hours, unless it could do even better with an MOI of REDACTED which it decided in May 1990 it could not (SB Br. 15-16). But this factual scenario is contradicted by overwhelming evidence. Before trial, Didelez testified that "none of the experiments after September '89 [and before June 1990] allowed [him] to draw any conclusions with respect to kinetics" (Didelez dep. 764). That testimony applies to the October 1989 trial of REDACTED. In his March 2, 1990 status memorandum, Didelez articulated that either REDACTED or REDACTED was "most plausible" (PTX56; OB 20-21). The document did not say that REDACTED looked good, but REDACTED might be better. In a June 19, 1990 memorandum (PTX61), Didelez characterize the results from the REDACTED MOI trial in October 1989 as "very disappointing (PTX61).

***10** SB admits that after June 1990 it did no further work on MOI until January 1991--after Biken's visit to SB (SB Br. 16-17). All the trials in the interim were with REDACTED MOI, leading me to conclude that SB had not decided upon REDACTED (PTX183).

4. The Admitted "Failure" as of June 1990

Didelez on June 19, 1990 gave management a "succinct summary of the development work conducted since '88" (PTX61). That memo did not report that SB had actually resolved any of the issues that had been the subject of its experiments. He gave no "most plausible scheme." On kinetics, Didelez reported, based on the work conducted prior to fall 1989, that "the maximum amount of infectious titer is reached around REDACTED" and an MOI of REDACTED. He did not suggest that any different conclusion had been reached from the October 1989 test of REDACTED. As noted above, he characterized the pfu titer from that condition as "very disappointing" (PTX61). On clarification, Didelez expressed that "it is possible to clarify ... by REDACTED ... with results comparable to clarification by REDACTED (PTX61). Didelez preferred REDACTED for practical reasons and because it posed less risk of contamination (Didelez dep. 617-18).

Didelez directed the remainder of his summary to the BSA problem, apprising management that the effort to reduce BSA "is now a failure" (PTX61). At that point, SB had spent about a year and a half attempting to solve the BSA problem by the use of REDACTED in lieu of FBS. Didelez theorized about the role of BSA, but had no answer, and said that, "[b]efore pursuing the development it is still necessary to determine whether REDACTED works" during cell culture or virus harvest (PTX61). While Didelez was unsure about how to address the BSA problem, he had reason to believe that Biken had done so successfully (PTX61). In July 1989, SB obtained samples of Biken's vaccine which it tested for BSA and pfu's (PTX38, PTX73). Those tests indicated that Biken had achieved both low BSA and high pfu's. Thus, Didelez in his June 1990 memorandum tellingly wrote, "It would be very useful in comparison to know what Takahashi has done." (PTX61).

5.

The evidence does not support SB's assertions that it had resolved the problem of low pfu's, separately or otherwise. The three steps that SB cites as having increased pfu's did not succeed, and SB was not able to achieve its objectives. As Thysman admitted, the results of the fall trials were all unacceptable (Thysman dep. 507, 511-12, 521, 558-60, 589-90, 652-53, 656). No data shows that pfu's "steadily" increased as the fall 1990 trials progressed (SB Br. 22), despite SB's statement to the contrary (SB Br. 22).

SB made at least one change which may have succeeded in giving high pfu's--the change to REDACTED using Biken's conditions (Tr. 1007-09). By this change did not occur until after the Biken visit, and I find that SB must have learned this key step from Biken in that visit. SB had not settled upon the REDACTED parameters by December 6, 1990, had not tested different REDACTED at all, had never tested REDACTED (Biken's conditions) (Tr. 2190-92), and had not even decided to REDACTED rather than REDACTED (PTX61; C7.8; Didelez dep. 1010 29). SB admits that it had not completed its development work prior to Biken's visit. It admits that "work that needed to be completed prior to beginning the consistency lots concerned the REDACTED step and a test combining all of the final parameters that SB independently developed" (SB Br. 24). [FN7]

> FN7. Without addressing the law at this point, I note that SB's "publication" defense for this step must fail on the facts: REDACTED was published in November 1993 while SB first used those parameters in December 1990--after observing Biken's process.

G. The Visits to Biken

1. The December 6, 1990 Visit

***11** In the fall of 1990, SB decided to seek Biken's assistance. On October 31, 1990, Stephenne initiated a request to Takahashi through Dr. Dirk Teuwen to "share with us an update on the method of bulk production for the OKA strain as well as the lyophilisation process currently applied at Handai-Biken" (PTX89). At a meeting shortly thereafter, SB arranged that Biken personnel would come to SB's Belgian facility on December 6 for a meeting that "would allow us to bring together our people from clinical and production to review with Takahashi and Takeo Konobe various aspects on varicella" (PTX92). A draft agenda, provided to Didelez and D'Hondt on November 19, called for a presentation by Biken of its "OKA vaccine production characteristics" (PTX94).

As of 1990 when SB sought Biken's help, Biken had vast experience in the commercial production of vaccines, and actually was producing on a regular basis large amounts of varicella vaccine. SB's claim that it was not seeking help from Biken when it asked for extensive information on Biken's process is implausible and not supported by any evidence. According to Stephenne, his principal interest was "to check whether they [Biken] have something better than us or not" and "the only thing we were doing is to compare to what they were doing" (Stephenne dep. 139, 152). Teuwen confirmed that Stephenne, who initiated the requests to Biken, wanted to "be able to observe all steps of the manufacturing" and "look the steps on the varicella production" (Teuwen dep. 180, 201).

On December 6, 1990, Takahashi, Konobe, and Iwao Yoshida from Bike made a presentation to Didelez and others from SB of the Biken production method used to make its successful vaccine. Biken presented a detailed flow diagram of its process by way of slides that were then given to SB, and "reviewed the different steps of the production" (PTX105; Didelez dep. 279, 939). Didelez and others took detailed notes, recording the kinetics, washing, and clarification schemes (PTX106; Didelez dep. 1031-35). SB was able to and did ask questions (Yoshida dep. 136).

SB was also "interested by the consistency of the [pfu] results from batch to batch," which SB thought "was very, very consistent" (Didelez dep. 279-80). Didelez testified that the SB personnel "were quite impressed by these consistent results and so we realized that we had some progress to make in that field" (Didelez dep. 281). It was confirmed during the meeting that Didelez and Duchene would travel to Japan.

Following the meeting, Didelez "transferred [the Biken] slides to my team and we have certainly reviewed the slides in detail" (Didelez dep. 295). The team paid attention to both similarities and

differences (Didelez dep. 935; Thysman dep. 694, 698), so that SB could focus its efforts on differences that might account for Biken's success (Didelez dep. 941). Biken's process had enough commonalities with SB's efforts that SB was able to identify and make changes quickly. As Dr. Daniel Wang explained, SB "did not see anything on the flow sheet ...--any piece of equipment, or any process in there--which is outside of the realm of what SmithKline is able to practice" (Tr. 993).

***12** Before the Biken visit, Didelez had investigated and found that Biken's vaccine had both high pfu's and low BSA (PTX38; PTX73; Didelez dep. 1041-42), which SB had been unable to obtain in combination. The Biken visit showed Didelez that, to achieve high pfu's and low BSA, Biken had not had to resort to a REDACTED proposed by D'Hondt (PTX95)) and, instead, had achieved success by use of REDACTED to remove BSA and REDACTED to maintain potency (Tr. 997-1000, 1007-09). Because SB had experimented with REDACTED REDACTED, it was able quickly to settle on that approach from among the options it had considered (Tr. 997-98). It was also able quickly to test and incorporate Biken's REDACTED technique.

On December 6, 1990, immediately after the Biken presentations and following the team's discussion of the Biken procedure, Thysman directed a technician, Etienne De Waele, to run the Biken bulk vaccine procedure in trial 061290EVA (Didelez dep. 998). The December 6 trial involved certain "comparative points studied" (PTX110), most notably comparison of REDACTED schemes: SB's standard varicella REDACTED--(denominated "reference"); Biken's REDACTED which the technician specifically attributed to "BIKEN"; and REDACTED which had been Didelez's preference because "we use [it] in all the other vaccines so we had more experience and it is more practical" (Didelez dep. 999).

The December 6, 1990 trial was the SB's team's first with REDACTED--which was significantly different than SB's standard REDACTED condition. In particular, REDACTED REDACTED (Tr. 988). SB got further data about the significance of the different REDACTED schemes during the January visit to Biken which soon followed.

As to kinetics, Biken's presentation on December 6, 1990 of its detailed process diagram contained all the information necessary for SB, an experienced vaccine manufacturer, to determine that Biken successfully used an MOI of REDACTED and incubation of REDACTED in its final viral passage (PTX105). As Wang explained at trial, the information in Biken's diagram was all SB needed to make a reasonable assumption that the bottles Biken used were only about REDACTED infected, so that Biken's MOI in its final viral passage was REDACTED (Tr. 954-56). Even if SB did not figure this out, however, I believe it must have learned that Biken was using an MOI substantially REDACTED because, if SB had assumed that Biken's infectivity was REDACTED, the MOI would then have been REDACTED, and an infectivity of less than REDACTED would result in an even lower MOI (Tr. 954-55).

Notably, on January 3, 1991, SB ran a light kinetics trial in which it tried the preferable, more diluted MOI successfully used by Biken REDACTED harvest (Tr. 2277-80). This was the first SB trial using REDACTED since the fall of 1989. SB began its first potential consistency lot, VA101, on January 17, 1991. Didelez acknowledged that January 1991 was the first time SB used in combination all the steps selected for VA101 (Tr. 2306). For VA101, SB selected kinetics like Biken's with an MOI of REDACTED and REDACTED with the Biken conditions, although SB's preference had been for REDACTED, and its trials before the Biken visit gave just as good results with REDACTED (Tr. 664, 669, 672-73). SB does not deny that the REDACTED parameters it adopted after Biken's visit were precisely the same as Biken's.

***13** SB argues that Biken did not state the REDACTED it used for REDACTED and, therefore, Biken's REDACTED conditions were meaningless (SB Post-Tr. Br. 37-38). But Biken's flow diagram did contain the only information SB needed (REDACTED) to see that Biken's REDACTED conditions differed from SB's and to adopt Biken's. SB had to believe that its REDACTED equipment was comparable to Biken's, given the volumes involved, so all SB had to do was "go straight ahead and do the REDACTED" in its own equipment, REDACTED REDACTED (Tr. 162-63). [FN8] Indeed (and perhaps most telling),

SB specifically attributed REDACTED condition to "BIKEN" in its December trial right after the Biken visit (Tr. 2147). This fact alone refutes SB's claim that it "was lacking critical information necessary ... in order to compare the Biken process to the SB process" (SB Br. 38)--immediately following the Biken visit, SB made that exact comparison. The Biken REDACTED conditions were significantly different from any conditions tested previously by SB, involving only REDACTED applied under SB's conditions REDACTED. Use of such conditions by Biken was counterintuitive, as Wang testified (Tr. 1007-09).

> FN8. There are only a few designs of REDACTED equipment capable of handling the volumes being used by Biken and SB; a person familiar with REDACTED could estimate the REDACTED (Tr. 160-62).

SB also does not assert an independent development story with respect to REDACTED. Didelez testified only that he does not remember how SB ended up selecting the identical Biken conditions REDACTED (Tr. 2148-49). SB's speculation that it simply set its REDACTED (SB Br. 38) and by coincidence ended up with the Biken technique is not credible. No SB witness previously made this alleged "logical" speculation (SB Br. n.41), which is based on one clear misstatement of fact--that its December 6 test compared Biken's "REDACTED against conditions REDACTED" (id.). The comparison was to SB's standard condition of REDACTED (PTX110). Thus, while SB attempts to explain the change in REDACTED, it fails to explain the important change from REDACTED.

2. The January 1991 Visit

In late January 1991, Didelez and Duchene went to Biken's production facility in Kanonji (PTX254). During the five days, they were able to observe most steps of Biken's production process, and received descriptions and other information about the process steps that they were unable actually to observe (Tr. 799-800, 803-04). When not observing the production process, they met with Biken personnel to discuss the process and have questions answered (Tr. 804; Akiyama dep. 314-15). The Biken employees had been instructed by Dr. Fukai, the chairman of Biken, to provide whatever information SB requested (Tr. 790).

One subject discussed was Biken's REDACTED of the bulk vaccine by REDACTED. As reflected in Biken employee Terumasa Otsuka's notes (PTX254), SB asked about the relationship between REDACTED. In response, Biken provided the results of a study (PTX254) showing that REDACTED resulted in significantly less potent bulk vaccine (Tr. 812-13). SB saw the REDACTED process (Tr. 812) and specifically asked about the REDACTED, which caused the Biken personnel to take them to a room in which equipment catalogs are kept and show them the REDACTED catalog (Tr. 813-14). That catalog showed, among other things, the REDACTED (Tr. 814-15). SB asked specifically whether REDACTED was preferable (Tr. 811). While Otsuka did not recall the details of that discussion, his personal view was that REDACTED was the better method (Tr. 888). Biken also discussed its kinetics with SB, and how Biken's experiments had shown that its parameters were optimal (PTX124).

***14** Following the visit to Biken, Didelez and Duchene prepared a report of their trip for their superiors, including Stephenne. The cover page stated:

> The purpose of the visit was to observe a bulk Varicella production and the pertinent QC in detail.
> It is unfortunate that this visit took place so late and that nobody from SKB had ever visited the Kanonji factory previously.
> It is in fact quite clear a posteriori that precious time could have been saved both in production as well as in QC if this visit had been made several years ago. [FN9]

> FN9. Didelez claimed at trial that the time savings referred to was related to the time SB spent speculating as to whether Biken's process was superior (Tr.2008-09). I find this reading to be highly tortured, in conflict with the plain language written, and not credible. (PTX124).

The report notes that the Biken process "complies exactly" with the process description SB had previously received and states, "We were able to observe in detail the successive operations and eliminate the last remaining doubts, and come away with a certain number of important operational

details." (PTX124). With respect to REDACTED the trip report notes: REDACTED important to limit losses: see attached REDACTED table. (PTX124). The report thus confirmed that the REDACTED was important to limit the loss of potency, and elsewhere the report noted that the loss "is REDACTED," and referenced specifically to attachment 3 the charts which Biken provided showing the correlation between REDACTED. The fact that Didelez recorded Biken's REDACTED conditions as being REDACTED, is further acknowledgement that he felt it was unnecessary to do so because their equipment was comparable.

With respect to kinetics, the report confirmed that Biken's split ratio of REDACTED was "optimal" [FN10] and that the "maximum infectious titer in released vitus [i.e. for the last viral passage] was not reached until REDACTED:"

FN10. Biken's REDACTED equated to an MOI of REDACTED (Tr. 954-55).

Experiments done with the REDACTED MOIs showed that REDACTED. The REDACTED applied today seems optimal. REDACTED (PTX124).

The trip report prepared by Didelez and Duchene expressly states that SB was able to "eliminate the last remaining doubts, and come away with a certain number of important operational details," and indicates that the elimination of "remaining doubts" refers to the use of REDACTED and the split ratio REDACTED, both of which SB had learned about from Biken in early December and thereafter incorporated into its first production lot (PTX124). The reference to "important operational details" indicates that SB learned some additional information of value, and the memo on its face confirms the savings of time as a result of the information received from Biken (PTX124).

II. ANALYSIS OF MERCK'S MISAPPROPRIATION CLAIM

A. Choice of Law

Choice of law is an issue that need not be resolved. No party has pointed to any substantive difference in the laws of the various states having some contact with the matters at issue. No single state has "the most significant relationship" to the matters at issue. See Travelers Indem. Co. v. Lake, Del.Supr., 594 A.2d 38, 47 (1991) (citing Restatement (Second) of Conflicts § 145). Two of the parties are incorporated in Delaware, one in New Jersey, one in Pennsylvania and one in Belgium. The FDA, to which SB has made filings which include trade secret disclosures, is in Maryland. California and New York are where SB conducted clinical trials. And SB's Phase III clinical trial apparently is being conducted in a number of locations (Pietrusko dep. 16-17). The conduct that Merck seeks to prevent (marketing of SB's varicella vaccine) will occur throughout the United States and Canada. Another relevant factor on choice of law, the place where the parties' relationship is centered, does not suggest any particular state--Merck is a New Jersey corporation and the "relationship" giving rise to its claims is the agreement under which it has exclusive United States and Canadian rights to the Biken know-how.

***15** Insofar as it is necessary to resolve the choice of law, these factors lead to application of the Uniform Trade Secrets Act ("UTSA"), which codifies the basic principles of common law trade secret protection and has been adopted by over forty states, including Delaware (6 Del. C. §§ 2001-09), Maryland (Md.Code Ann., Commercial Law §§ 11-1201 to 11-1209), and California (Cal. Civ.Code §§ 3426 to 3426.11). Pennsylvania law does not apply, because only a single factor (one defendant is a Pennsylvania corporation) favors its application. Therefore, to the extent I must rely on a particular jurisdiction's substantive law, I will rely on the UTSA.

B. Biken's Process Know-How is a Trade Secret

A process is a trade secret if it derives independent economic value from not being generally known to, and not being readily ascertainable through proper means by, other persons who can obtain economic value from its disclosure or use, and is the subject of efforts to maintain its secrecy that are resonable under the circumstances. 6 Del. C. § 2001(4); Miles, Inc. v. Cookson America, Inc., Del. Ch., C.A. No. 12310, 1994 WL 676761, Hartnett, J. (Nov. 15, 1994). The Biken process meets all the elements of a trade secret.

1. The Biken Process is a Valuable Commercial Process

A commercial production process consisting of a "combination of the principles and details used to make a product" can be a trade secret, as can elements of the process. Miles, 1994 WL 676761. The combination of steps into a process is a trade secret, even if all the component steps are known, so long as it is a "unique process which is not known in the industry." Salsbury Labs., Inc. v. Merieux Labs., Inc., 735 F.Supp. 1555, 1569 (M.D.Ga.1989), aff'd, 908 F.2d 706 (11th Cir.1990); see also Miles, 1994 WL 676761, at *11; accord, Imperial Chem. Indus. Ltd. v. National Distillers & Chem. Corp., 342 F.2d 737, 742 (2d Cir.1965) ("A trade secret can exist in a combination of characteristics and components, each of which, by itself, is in the public domain, but the unified process, design and operation of which, in unique combination, affords a competitive advantage and is a protectable secret.") This principle simply recognizes that the choice of individually known components and techniques to create a working manufacturing process is often, as here, a difficult undertaking. Where at individual steps of a process there are a variety of alternatives, the choice made through much effort of specific ingredients, materials, conditions, and steps in an actual, working process constitutes a trade secret. See, e.g., Salsbury Labs., 735 F.Supp. at 1569.

The changes needed to convert a known laboratory process into a manufacturing process can constitute protectable trade secrets. For example, in Salsbury Laboratories, the court found that plaintiff's commercial process for manufacturing an avian vaccine was a trade secret even though laboratory production methods were generally known. Id. On appeal, the Eleventh Circuit noted that "producing MG-BAC on a commercial scale was a novel accomplishment which took several years to achieve," that the existence of small-scale method did not change:

> ***16** Nor was the development of MG-BAC merely an extension of the existing methods of producing an MG vaccine on a small scale.... While the autogenous MG vaccine provided the basis for commercial development, there is ample evidence that much time, labor and money were expended by plaintiff in developing a new process and product.

Salsbury Labs., 908 F.2d at 711.

In Monovis, Inc. v. Aquino, 905 F.Supp. 1205 (W.D.N.Y.1994), the court held that trade secret protection extends to the practical problem-solving that enables commercial application of theoretical concepts:

> Zimmern's Know-How serves as a guide, charting the way through the many problems and decisions faced in designing a single-screw compressor and developing a practical manufacturing technique.... To date, Zimmern and his licensees are alone in having successfully maneuvered the entire course and achieved commercially-viable single-screw compressors.

Id. at 1231. As the court pointed out, "Zimmern does not claim to be the 'inventor' of the single-screw compressor. He credits past scientists such as DaVinci and Archimedes with the initial concepts underlying the screw. What he does claim responsibility for is solving the hundreds of practical problems encountered in actually building a working single-screw compressor, as opposed to merely appreciating the possibility in general or theoretical terms." Id. at 1216.

Biken developed a successful commercial production process for varicell vaccine and used that process to manufacture large amounts of high potence vaccine beginning in late 1986. That process is indisputably valuable.

2. The Biken Process is Not Generally Known or Readily Ascertainable by Proper Means

Under the Uniform Trade Secrets Act, information is not a trade secret if it is generally known to, or readily ascertainable by proper means by, others. 6 Del.C. § 2001. This also is the standard under the Restatement of Torts. Milgrim On Trade Secrets § 1.07[2] at 1-349. The mere fact that aspects of a trade secret process can be found in publications does not mean that the process is not a trade secret. For this reason, courts have rejected the argument that one who has learned particular information from a trade secret process is not liable if it can show that the information learned is somewhere "published":

> [Defendants] thus argue, for example, that because the Chilton Patent is "in the public domain," Zimmern cannot claim as a trade secret any aspect which his manufacturing method has in common

> with that discussed in such patent. This argument is premised on an overly restrictive view of trade secret protection which this Court rejects. It is, as earlier noted, only because of Aquino's confidential relationship with Zimmern (and the litigation its breach has generated) that the defendants are now able to select particular items from a vast sea of public information and contend that they "could" have divined therefrom the needed critical information; such is the very approach rejected in Franke v. Wiltschek, supra. Items such as the Chilton Patent were publicly available, but were by no means obvious; they were not accompanied by instructions explaining where they were useful and where they were not, or what particular elements they described were relevant and helpful and which were not, or indeed why they should be selected over some other publicly available information. It is this type of knowledge which is the heart of Zimmern's Know-How.

***17** Monovis, Inc. v. Aquino, 905 F.Supp. 1205, 1228 (W.D.N.Y.1994) (emphasis added); accord, Rohm and Haas Co. v. Adco Chem. Co ., 689 F.2d 424, 433 (3d Cir.1982). Because a process consisting entirely of generally known elements is protectable as a trade secret, id. at 433-34, the value of trade secrets would be lost if a defendant could obtain the process, learn thereby the important choices made by the trade secret owner at various process steps, use the information gained for its benefit, and avoid liability by then saying that the particular information used is "published."

In Monovis, Inc., defendants argued that two patents disclosed "much" of the claimed trade secret for manufacturing single-screw compressors. Although the court agreed that the references disclosed some of the elements of the process, it held that more was needed:

> [T]he defendants have not explained how an engineer uneducated in Zimmern's processes would be led to the [Redacted] process or the [Redacted] method by studying the patents; indeed, Zimmern's Patent would likely discourage the engineer from using the scraping method described by Chilton. In short, it is only because the defendants have been exposed to Zimmern's method that they have been able to locate public documents that make references, often oblique or disparaging, to elements of Zimmern's secret manufacturing method.

Id. at 1227 (emphasis added); see also id. at 1228 (armed with the trade secre information, defendants "are now able to select particular items from a vast sea of public information and contend that they 'could' have divined therefrom the needed critical information"). The court also rejected defendants' claim that the "Chilton patent" negated plaintiffs' trade secret claim, in part because the patent did not lead to a viable commercial process: "Chilton's patent was merely a 'paper patent' describing a process that has not--and could not--be used to successfully produce a commercially-viable screw because it embodied a mistake that Zimmern had remedied." Id. at 1226.

In Rohm & Haas, 689 F.2d at 424, the court required defendants to do more than point to individual elements of the trade secret process in the literature. In fact, defendants' own expert admitted that neither he nor defendants knew of the publications before the lawsuit. Id. at 431 & n.5 (citing Heyden Chem. Corp. v. Burrell & Neidig, Inc., 64 A.2d 465, 467 (N.J.1949) ("The truth is, of course, that only a person who knew the ... process could make the selection of literature references which were offered in evidence.")). The court found that plaintiff had established the existence of a trade secret, noting that there was "no reason to suspect that defendants could have duplicated the Process through skill and effort using the available literature." Id. at 431.

The three cases cited by SB to support its "publication" defense turned on their particular facts and are not relevant here. In American Airlines, Inc. v. KLM Royal Dutch Airlines, Inc., 114 F.3d 108 (8th Cir.1997), the plaintiff attempted to change its definition of its trade secret from a combination of five elements comprising a yield management system to a combination of four of those elements The District Court granted summary judgment because there was no evidence the defendant had received "any detailed algorithms or formulae describing how the five demand forecasting elements were to be incorporated, but had only received four of the general elements at the conceptual level without information as to how the concepts were to be combined." 114 F.3d at 110. In American Can Co. v. Mansukhani, 742 F.2d 314 (7th Cir.1984), the alleged trade secrets were formulas for certain inks. However, the Court found that a patent "disclosed each of the ingredients (except dyes) in

the trade secret formulas, and proportions for these ingredients," 742 F.2d at 327, and that, under those circumstances, the trade secret could only consist of "precise proportions of the ingredients," id., and because the defendants' precise proportions were different, there was no trade secret misappropriation. In Flotec, Inc. v. Southern Research, Inc ., 16 F.Supp.2d 992 (S.D.Ind.1998), the Court found that the defendant had not used any information received from the plaintiff but instead had developed its process independently through reverse engineering. Id. at 1008.

***18** SB has not cited any case in which a court has allowed what SB has done--gained valuable information from access to a trade secret process and attempted to avoid liability by pointing to some publication of the particular information used. What the cases such as Monovis, Salsbury, and Rohm & Haas hold is that a trade secret process can consist of a combination of steps each of which has been publicly disclosed, and a defendant that has had access to such a process may not evade misappropriation on the basis that particular information learned from its access could be found in a publication.

The references that SB claims render the Biken Know-How "generally known" or "readily ascertainable" are similar to the rejected references in Salsbury Laboratories and Monovis, and, at best, relate to laboratory approaches for making a varicella vaccine. They do not indicate that they are in fact used for commercial vaccine production, that they could be used for commercial production, or that they solve the practical problems that would be encountered in a manufacturing environment.

Nothing in several publications by Takahashi during the 1970's cited by SB discloses specific information in Biken's commercial process used by SB. Those 1970's publications (TX1393; TX1400, TX1527) concern the laboratory process developed by Takahashi, and not Biken's commercial process that was developed in the 1980's by people other than Takahashi (Tr. 842-43).

Biken's '726 patent application from 1993 describes the formulation of a improved stabilizer for varicella vaccine; it does not purport to disclose commercial production process (Tr. 194-95). Example 2 describes the use of 2 Roux bottles (TX1465), to make 150 to 400 ml. of vaccine, which is too small for commercial process (Tr. 195-96). Example 2 also differs in numerous respect from Biken's actual commercial process--REDACTED (Tr. 196-97). For these reasons, nothing in the patent suggests that the brief description in Example 2 is part of Biken's or anyone's commercial production process.

Merck's '736 patent (TX1476) does not publish Biken's REDACTED method for several reasons. First, as Dr. Provost testified, that statement was not in the context of any commercial process, but described the manner in which REDACTED (Tr. 367). A statement in the patent plainly confirms Provost's testimony: REDACTED Second, the patent describes other REDACTED methods: REDACTED

This statement appears in the "Detailed Description of the Invention," which makes it clear that REDACTED was not being disclosed as the preferred method. In addition, the patent discusses other REDACTED parameters in other examples (TX1476; Tr. 372). Finally, the Merck patent makes no reference at all to Biken, and therefore would not be read as a disclosure of information about Biken's commercial process.

Nothing in the publications indicates that either the REDACTED steps described are actually used in Biken's commercial process or any commercial process. SB offered no testimony that one skilled in vaccine production could reach any conclusion from these publications. SB chose not to call its expert witness on publications (Dr. Griffiths) at trial.

***19** Because the ability to produce a varicella vaccine commercially and the practical knowledge needed to implement the production is at the heart of the Biken know-how, the references cited by SB do not render the know-how generally known or readily ascertainable. Courts have uniformly rejected efforts by trade secret defendants to argue that a process is generally known or readily ascertainable by pointing to elements in the published literature only after the defendant has been exposed to the trade secret information.

Section 8.03 of the SB/Biken agreement removes a confidentiality obligation to the extent Biken information ceases to be secret. Because no

publication discloses either Biken's process or any particular step actually used in Biken's process, Section 8.03 gives SB no greater right to use or disclose information.

3. Biken Has Taken Reasonable Efforts to Maintain the Secrecy of its Process

Biken has made reasonable efforts to maintain the secrecy of its commercial production process. It imposes secrecy obligations on its employees, and greatly restricts access to its production operation (Tr. 785-86). Except for its "publication" arguments, SB has not claimed that Biken's efforts to maintain the secrecy of its process are deficient in any way.

C. SB's Efforts to Market its Varicella Vaccine in the United States and Canada Constitute Misappropriation of Biken Know-How

Unauthorized use of trade secret information and unauthorized disclosure of trade secret information constitutes misappropriation. 6 Del. C. § 2001(2); Miles, 1994 WL 676761, at *9; A.L. Labs., Inc. v. Philips Roxane, Inc., 803 F.2d 378 (8th Cir.1986), cert. denied, 481 U.S. 1007 (1987); General Elec. Co. v. Sung, 843 F.Supp. 776, 778 (D.Mass.1994). Unauthorized use includes use by one who acquired the trade secret "under circumstances giving rise to a duty to ... limit its use." 6 Del. C. § 2001(2)(b)(2)(B). Thus, even though SB was entitled in 1990 to obtain Biken's process information, use of that information outside the contract territory (Japan, Korea, the United States, and Canada) constitutes misappropriation.

D. SB Used Biken's Trade Secrets to Guide the Development of its Vaccine

Trade secret protection "extends not only to the misappropriated trade secret itself but also to materials 'substantially derived' from that trade secret." General Electric, 843 F.Supp. at 778. A process developed with "explicit reference" to the trade secrets is substantially derived from the trade secrets. Id. at 779. See Mangren Research & Dev. Corp. v. National Chem. Co., 87 F.3d 937, 944 (7th Cir.1996) ("defendants misappropriated Mangren's trade secrets even if defendants created a new product if defendants could not have done so without use of Mangren's trade secret"); In re Innovative Constr. Sys., Inc., 793 F.2d 875, 887 (7th Cir.1986) ("Were the law of trade secrets not flexible enough to reach the modifications in the instant case, when it is evident that the formulas were substantially derived from Innovative's, it would indeed be hollow.").

***20** Misappropriation occurs even where the trade secret is used only as a starting point or guide in developing a process. See, e.g., Black, Sivalls & Bryson, Inc. v. Keystone Steel Fabrication, Inc., 584 F.2d 946 (10th Cir.1978) ("Based on the evidence, a jury could reasonably infer that [the trade secret] was helpful to Smalling as a starting point for his calculations .... If nothing else, a jury could find that Smalling did not have to experiment with the broad range of disclosed coefficients to determine the proper starting point."); Reinforced Molding Corp. v. General Elec. Co., 592 F.Supp. 1083 (W.D.Pa.1984) (noting that "during the days [defendant's engineer] spent observing the manufacturing of the brace parts, he acquired knowledge which later greatly assisted Defendant in subsequently manufacturing the parts themselves," and holding "If nothing else, Plaintiff's research and design were used as a starting point for Defendant's product development."); accord, 4 Milgrim on Trade Secrets § 15.01[1][d][vii] at 15-89 ("a plaintiff may prevail on a trade secret claim by establishing that defendant used plaintiff's trade secret as the helpful starting point for defendant's own development efforts").

Misappropriation also occurs where a defendant uses a plaintiff's trade secrets to understand "what pitfalls to avoid." See Affiliated Hospital Products, Inc. v. Baldwin, 373 N.E.2d 1000, 1006 (Ill.App.1978), ("Even accepting their denial of any literal copying of MPL drawings, these drawings aided defendants in the design of Hypomed machinery, if only to demonstrate what pitfalls to avoid"); see also Glaxo Inc. v. Novopharm Ltd., 931 F.Supp. 1280, 1299 (E.D.N.C.1996) ("A trade secret need not necessarily be comprised of positive information, such as a specific formula, but can include negative, inconclusive, or sufficiently suggestive research data that would give a person skilled in the art a competitive advantage he might not otherwise enjoy but for the knowledge gleaned from the owner's research investment."), aff'd, 110 F.3d 1562 (Fed.Cir.1997).

"Misappropriation of trade secrets may be proven by circumstantia evidence," see Miles, 1994 WL 676761, at *13, and more often than not, "plaintiffs must construct a web of perhaps ambiguous circumstantial evidence from which the trier of fact may draw inferences which convince him that it is more probable than not that what plaintiffs allege happened did in fact take place." Greenberg v. Croydon Plastics Co., 378 F.Supp. 806, 814 (E.D.Pa.1974). Here, both direct and circumstantial evidence establish SB's use of the Biken know-how to guide its own development of its process.

The fact that SB sought and obtained Biken's assistance, and the fact that SB's personnel responsible for developing its process were the ones who became familiar with Biken's trade secret technology, "give[s] rise to a compelling inference that [SB's process] was substantially derived from [Biken's] trade secrets." General Electric, 843 F.Supp. at 779; see also USM Corp. v. Marson Fastener Corp., 467 N.E.2d 1271, 1284 (Mass.1984).

***21** Courts are skeptical of an independent derivation defense where--after being exposed to the trade secrets--the defendant has a "purportedly epiphanic episode." American Can Co. v. Mansukhani, 814 F.2d 421, 426 (7th Cir.1987). For example, in Monovis, the court rejected defendants' independent derivation defense, pointing out that if defendants had already developed their own compressor--as they claimed--they would not have needed plaintiffs' information. See 905 F.Supp. at 1215-16. The court also pointed out that, even after receiving plaintiffs' trade secret information, defendants asked to visit one of plaintiffs' manufacturing facilities, bringing with them a "list of topics we would like to discuss." Id. at 1219. The court observed that: "The fact that [defendant] still had questions ... is more probative than whether he received immediate answers." Id.; see also FMC Corp. v. Varco Int'l, Inc., 677 F.2d 500, 503-04 (5th Cir.1982) (after experiencing difficulty in duplicating plaintiff's product, defendant hired plaintiff's former employee who had the requisite "competitive background").

Monovis is similar to this case. The defendants had obtained the trade secret information under a licensing agreement. Taking what the court described as a " 'deny everything' approach," Monovis, 905 F. Supp at 1231, the defendants argued that their method of production was different, id. at 1232, that they had essentially completed their work before getting access to the know-how, id. at 1214-15, and that all of the specific information the plaintiff claimed as know-how could be found in assorted publications or patents, id. at 1225-26. As noted, the court rejected the "publication" defense. It also found that the defendants' denial of use was refuted both by the circumstantial evidence (in particular the fact that the defendants sought the plaintiff's assistance), id. at 1219, and by the contemporaneous documents reflecting the assistance received, id. at 1220. And while the defendants' process was different, the court found the use of the trade secret know-how to have provided both "a guide, charting the way through the many problems and decisions," id. at 1231, and "a springboard" to the solution of the problems, id . at 1232.

Also analogous is Salsbury Laboratories, Inc. v. Merieux Laboratories, Inc., 735 F.Supp. 1555 (M.D.Ga.1989), aff'd 908 F.2d 706 (11th Cir.1990). The court found misappropriation of both the entire process and specific aspects of the process: "In addition to the overall production process, the court finds that the fact Salsbury uses certain ingredients and methods during each step of its process constitutes trade secret information." Salsbury, 735 F.Supp. at 1569. The court then found that the defendant's use of specific steps learned from Salsbury constituted trade secret misappropriation including: the use of "a particular potency scoring test," id., even though there were published articles concerning that test, id. at 1565; the use of Salsbury's unique medium, id. at 1569, even though "various media in the public domain contain ingredients that are contained in Salsbury's medium," id. at 1563; the use of a particular inhibitor even though it was one of a number of generally available inhibitors, id. at 1564; and the use of a particular strain, id. at 1569, which was one of several strains available, id. at 1570.

***22** SB's independent development defense is unsupported. SB's assertion that it did not use any Biken know-how in its process or even seek help from Biken claiming instead that it had resolved all of its problems prior to December 6, 1990 is contradicted by SB's conduct, by its statements in communications to Biken, and by its own records. I

find that SB used Biken know-how in resolving its problems and finalizing its production process. Such conduct constitutes misappropriation of Biken's trade secrets.

E. Under its Agreement with Biken, SB is Prohibited from Using Biken Know-How to Produce a Vaccine for Sale in the United States and Canada

The licensing agreement between Biken and SB granted SB a license as follows:

> 2.01 The Foundation hereby grants to SK & F a nonexclusive right and license to use the Strain and Know-How to make, have made, use and sell the Vaccine in the Contract Territory.

(PTX551) § 2.01). The "Contract Territory" originally was "the countries of Europe" (PTX552, § 1.03) and, by subsequent amendments, was extended to "all the countries of the world except Japan, Republic of Korea, United States of America and Canada" (PTX568-569).

Under the agreement the licensed "Know-How" was defined as:

> without limitation, all technical information and know-how regarding preparation and propagation of the Strain and commercial production of the Vaccine which are presently in the possession of the Foundation or are acquired hereafter by the Foundation during the term of this Agreement.

(PTX552, § 1.05). The information that Biken provided to SB in 1990 and 1991 concerning commercial production, including its own production process, fell within the definition of Know-How. Accordingly, SB was only entitled to use that Know-How to make, use or sell its vaccine in the Contract Territory, and not in the United States or Canada.

The circumstances clearly indicated that the parties' intent was to limit SB to its Contract Territory--that was the extent of the license, SB was precluded from filing information with regulatory agencies except in the Contract Territory, and Biken was giving territorial rights to Merck and also keeping rights in Japan and Korea. SB points to nothing indicating that the parties intended that SB was not limited to its Contract Territory.

SB's claim that the licensing agreement allowed it to perform clinical trials "outside the contract territory, so long as SB did not commercially market a vaccine in such a territory before the Biken patents expired" (SB Br. 64-65) is unsupported. The agreement grants only a right "to use the Strain and Know-How to make, have made, use and sell the Vaccine in the Contract Territory" (PTX552, § 2.01). Using its vaccine in clinical trials unquestionably is a "use" limited to the Contract Territory, a conclusion reinforced by other sections of the agreement, which authorized SB "to pursue clinical evaluation and to seek appropriate government approvals to market the vaccine [ ]" (PTX552, § 5.01), but which limited-the disclosure of information in connection therewith to "governmental authorities within the Contract Territory" (PTX552, § 8.04).

***23** The territorial limitation continued even after the licensing agreement expired in 1995. The term of the Biken/SB licensing agreement was as follows:

> This Agreement shall continue to be effective in each country of the Contract Territory for a period of ten (10) years from the date of this Agreement or until the expiration or invalidation of the Patent in such country, whichever period is longer, unless otherwise terminated pursuant to the provisions hereof.

(PTX552, § 12.01). The agreement expired completely on March 12, 1995, upon the expiration of Biken's Belgian patent.

A trade secret is protectable for so long as it continues to be a trade secret--i.e., not generally known and not readily ascertainable. 2 Roger M. Milgrim, Milgrim on Trade Secrets § 8.02[6] at 8.21; 3 Roger M. Milgrim, Milgrim on Licensing § 27.01 at 27-2. It is because of this ability to protect valuable information indefinitely that commercial production processes (which cannot be discovered by reverse engineering or other scientific methods) are frequently protected as trade secrets rather than patented.

Because of the ability to protect trade secrets indefinitely, it is essential that a trade secret licensing agreement specify the rights of the parties with respect to the trade secret after expiration of the agreement:

> [I]f the parties to a trade secret license fail to indicate whether the licensee will be entitled to use the licensed matter beyond the contractual term of the license, they may later face the question of whether the licensee may continue use